



### **NATURE OF THE ACTION**

3. This is an action for patent infringement arising under the Patent Laws of the United States, including 35 U.S.C. §§ 271, *et seq.*

### **JURISDICTION**

4. This Court has original and exclusive subject matter jurisdiction over patent infringement claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over GeneAlign. Upon information and belief, GeneAlign actively solicits and provides services to health care providers, physicians and patients in the Commonwealth of Massachusetts. GeneAlign, through its employees and agents, serves physicians and patients in Massachusetts through a highly-interactive website. Upon information and belief, GeneAlign specifically targets this District through the user-portal on its website that permits healthcare providers and physicians to access personal account information. In addition, GeneAlign is believed to derive revenues from the services and products rendered and/or offered in Massachusetts such that it should have reasonably expected to be subject to suit in this District.

### **VENUE**

6. Venue is proper in this District under 28 U.S.C. § 1400(b) because GeneAlign conducted and continues to conduct its business in the Commonwealth of Massachusetts in a manner that infringes on the methods protected by the patent in suit and, upon information and belief, has a regular and established place of business in the Commonwealth of Massachusetts. Specifically, upon information and belief, GeneAlign is engaged in a partnership through which it sponsors and conducts an ongoing clinical study in this District.

**UNITED STATES PATENT NO 8,455,194**

7. BHDx is a heart health management company providing integrated diagnostic and patient management solutions which advance cardiovascular disease risk assessment, monitoring, and treatment. BHDx's goal is to predict, prevent, manage, and reverse cardiovascular disease by improving patient assessment and management.

8. On or about June 4, 2013, United States Patent No. 8,455,194, which embodies diagnostic methods for detecting the susceptibility of an individual to statin-induced myopathy (the "'194 Patent"), was duly and legally issued by the United States Patent and Trademark Office, and is valid and subsisting. A true and accurate copy of the '194 Patent is attached hereto as **Exhibit A**.

9. The '194 Patent is owned by Isis Innovation Limited ("Oxford"), a technology commercialization company and wholly-owned subsidiary of the University of Oxford.

10. In November 2011, Oxford granted an exclusive license under the '194 Patent to BHDx thereby granting BHDx the right to use Oxford's Statin Induced Myopathy Genotype ("SLCO1B1") test (the "Oxford License Agreement").

11. Under the Oxford License Agreement, BHDx was granted an exclusive license to "develop, make, have made, use, import and Market the Licensed Product, and to develop, use, and Market the Licensed Service, in the Field and the Territory." Oxford License Agreement, § 2.1.

12. BHDx offers the SLCO1B1 test, protected by the '194 Patent, exclusively through its Framingham-based Clinical Laboratory Improvement Act ("CLIA") certified laboratory. The SLCO1B1 test identifies patients who are at higher risk for developing severe

myopathy (muscle aches and pain) as a side effect of statin drugs prescribed to reduce low-density lipoprotein cholesterol levels.

13. The Oxford License Agreement expressly grants to BHDx the right to bring this action for injunctive relief and damages. Specifically, Article 6 of the Oxford License Agreement grants BHDx the first right to take legal action against any misappropriation or infringement of the '194 Patent.

14. On November 22, 2013, the U.S. Patent and Trademark Office ("PTO") received a request for reexamination of claims 1 through 7 of the '194 Patent. On January 14, 2014, the PTO initiated reexamination.

15. On January 6, 2015, the PTO issued an Ex Parte Reexamination Certificate for the '194 Patent, re-issuing claims 1 through 7 as amended. Claims 8 through 14 were not subject to reexamination. Claims 15 through 25 were added during the reexamination. A copy of the Ex Parte Reexamination Certificate dated January 6, 2015, is attached hereto as **Exhibit B**.

16. The patented method of the '194 Patent, as amended during the reexamination, involves three principal steps: (a) an "assaying" step, (b) a "determining" step, and (c) an "administering" step.

**COUNT ONE: DIRECT INFRINGEMENT**  
**OF THE '194 PATENT**

17. The allegations set forth in paragraphs 1 through 16 are hereby realleged and incorporated as if set forth fully herein.

18. GeneAlign offers genetic testing that seeks to identify those patients who are at higher risk of developing statin-induced myopathy due to a variation on their SLCO1B1 gene (the "GA SLCO1B1 Test").

19. GeneAlign actively offers, markets, and sells the GA SLCO1B1 Test to patients and health care providers including physicians and pharmacists throughout the United States, including in this District.

20. In offering, marketing, selling, and performing the GA SLCO1B1 Test, GeneAlign infringes the '194 Patent directly and/or through inducement.

21. Upon information and belief, GeneAlign itself directly performs the “assaying” and “determining” steps of the method covered by the '194 Patent, when those claim terms are properly construed in accordance with the '194 Patent specification, prosecution history, and other evidence.

22. Among other things, GeneAlign provides physicians and pharmacists with GeneAlign’s collection kits that include its GeneAlign Lab Requisition Form for Pharmacogenetic (“PGx”) Testing (“GeneAlign’s PGx Form”) for requesting a complete genetic variation panel of SLCO1B1, a copy of which is attached as **Exhibit C**.

23. In response to receiving its GeneAlign PGx Form, clinical test reports, and other information provided by GeneAlign’s sales representatives and other agents, GeneAlign “determines” the appropriate dosage of a statin, within the meaning of the '194 Patent, for health care providers and clinicians.

24. For instance, through GeneAlign’s Clinician Decision Support (“GeneAlign’s Reporting Tool”), GeneAlign provides clinical guidance for medication dosing, which are correlated to the result of the assay that GeneAlign performs.

25. Through the detailed information, recommendations, and instructions provided to physicians and pharmacists, GeneAlign directs and controls physicians and pharmacists to perform the “administering” step of the patented method or acts in concert with physicians and

pharmacists, as a partner or joint venturer, and thus jointly performs the “administering” step of the patented method.

26. As a result of GeneAlign’s infringing activities, BHDx has suffered damage in an amount to be proved at trial.

27. In addition, GeneAlign’s infringement of the ’194 Patent is ongoing. Unless restrained and enjoined by the Court, GeneAlign will continue to infringe the ’194 Patent, causing BHDx irreparable harm.

**COUNT TWO: INDUCING INFRINGEMENT**  
**OF THE ’194 PATENT**

28. The allegations set forth in paragraphs 1 through 27 are hereby realleged and incorporated as if set forth fully herein.

29. GeneAlign offers, markets, sells, and performs the GA SLCO1B1 Test throughout the United States.

30. By using the GA SLCO1B1 Test, physicians and pharmacists directly infringe the ’194 Patent, and GeneAlign knowingly encourages and induces that infringement.

31. Without limitation, GeneAlign specifically markets and advertises the GA SLCO1B1 Test for use in identifying patients who are at risk of developing statin-induced myopathy. GeneAlign also employs sales representatives who actively instruct and encourage clinicians to order and use the GA SLCO1B1 Test.

32. GeneAlign further knowingly encourages and induces physicians’ and pharmacists’ infringement of the ’194 Patent by performing the “assaying” step of the patented method under their control and direction, pursuant to written agreements. For example,

GeneAlign enters into agreements with physicians and pharmacists to provide turn-key solutions for PGx testing through GeneAlign's PinPoint Partners program.

33. GeneAlign further knowingly encourages and induces physicians' and pharmacists' infringement by providing the GA SLCO1B1 Test, GeneAlign's Reporting Tool, clinical reports, and other information that instructs physicians and pharmacists and recommends appropriate statin dosages.

34. By this and other conduct, GeneAlign knowingly and actively induces physicians and pharmacists to administer statin dosages within the meaning of the '194 Patent.

35. GeneAlign engages in the above-described activity with actual knowledge of the '194 Patent.

36. GeneAlign engages in the above-described activity with the specific intent to induce physicians and pharmacists to infringe the '194 Patent.

37. As a result of GeneAlign's infringing activities, BHDX has suffered damage in an amount to be proved at trial.

38. In addition, GeneAlign's infringement of the '194 Patent is ongoing. Unless restrained and enjoined by the Court, GeneAlign will continue to infringe the '194 Patent, causing BHDX irreparable harm.

### **COUNT THREE: EXCEPTIONAL CASE**

39. The allegations set forth in paragraphs 1 through 38 are hereby realleged and incorporated as if set forth fully herein.

40. Pursuant to 35 U.S.C. § 287(a), BHDX has provided GeneAlign with notice of its exclusive rights under the '194 Patent.

41. Notwithstanding the notice provided by BHDx, GeneAlign continues to offer, sell, and perform the Infringing Test, thereby acting in reckless disregard of the likelihood that GA is directly infringing, jointly infringing, and/or inducing infringement of the '194 Patent.

42. Accordingly, GeneAlign's continuing infringement of the '194 Patent is willful and deliberate.

### **JURY DEMAND**

43. Plaintiff demands a jury trial on all issues so triable.

### **PRAYERS FOR RELIEF**

WHEREFORE, Plaintiff prays for relief as follows:

- (i) For entry of judgment by this Court that GeneAlign, its officers, agents, servants, employees, representatives, attorneys and all persons acting in active concert or participation with GeneAlign, have infringed the '194 Patent, either directly and/or by inducing others' infringement;
- (ii) For entry of an order by this Court enjoining and restraining GeneAlign, its officers, agents, servants, employees, representatives, attorneys, and all persons acting in active concert or participation with GeneAlign, from making, using, selling, or offering for sale the GA SLCO1B1 Test or otherwise infringing the '194 Patent;
- (iii) For entry of judgment by this Court awarding damages under 35 U.S.C. § 284 to compensate BHDx for GeneAlign's past, continuing or future infringement of the '194 Patent through the date such judgment is entered, including: (a) an accounting of all infringing acts; (b) treble damages for the exceptional case of GeneAlign's willful infringement under 35 U.S.C. § 284; and (c) BHDx's costs and attorneys' fees, plus interest, incurred in prosecuting this action under 35 U.S.C. § 285;
- (iv) For entry of an order requiring GeneAlign to surrender or destroy, within ten days from the entry of any final judgment or preliminary decree: (a) any and all property



which unlawfully violates the '194 Patent; (b) any and all product literature GeneAlign owns or possesses which unlawfully violates the '194 Patent; and (c) all other works owned by GeneAlign that infringe the '194 Patent;

(v) Such other and further relief as the Court deems just and proper.

**BOSTON HEART DIAGNOSTICS  
CORPORATION,**

BY ITS ATTORNEYS,

/s/ Wayne F. Dennison  
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**CERTIFICATE OF SERVICE**

I hereby certify that this document was filed through the ECF system and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: August 1, 2017

/s/ Wayne F. Dennison

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